Quality standards

Edition: BP 2025 (Ph. Eur. 11.6 update)

Salicylic Acid Cream

General Notices

NOTE: This monograph has been developed to cover unlicensed formulations.

Action and use

Keratolytic.

DEFINITION

Salicylic Acid Cream contains Salicylic Acid in Aqueous Cream.

The cream complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements. Where appropriate, the cream also complies with the requirements stated under Unlicensed Medicines.

Content of salicylic acid, C₇H₆O₃

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake 1 g with 10 mL of <u>water</u>, filter and add to the filtrate <u>iron(III)</u> chloride solution R1; an intense reddish violet colour is produced which persists on the addition of 6M <u>acetic acid</u>. Add <u>2M hydrochloric acid</u>; the colour disappears and a white, crystalline precipitate is produced.

ASSAY

Dissolve a quantity of the cream containing 0.25 g of Salicylic Acid in a mixture of 20 mL of <u>ethanol</u> (96%), previously neutralised to <u>phenol red solution</u>, and 20 mL of <u>ether</u> and titrate with <u>0.1M sodium hydroxide VS</u> using <u>phenol red solution</u> as indicator. Each mL of <u>0.1M sodium hydroxide VS</u> is equivalent to 13.81 mg of $C_7H_6O_3$.